Response to Office Action Mailed June 3, 2005

A. Claims in the Case

Claims 309, 311-315, 317-321, and 323-340 were rejected. Claim 316 was objected to as being dependent on a rejected base claim. Claims 309, 311-321, and 323, 324, and 326-341 are pending. Claim 309, 329, and 330 have been amended. Claim 325 has been cancelled without prejudice. Claim 341 is new.

B. Double Patenting

Claims 309, 311-321, and 323-340 were provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-39 and 173-174 of co-pending U.S. Patent Application No. 09/287,248. U.S. Patent Application 09/287,248 issued as U.S. Patent No. 6,908,770 on June 21,2005.

Claims 309, 311-321, and 323-340 were provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-39 and 173-174 of co-pending U.S. Patent Application No. 09/616,731,248. Applicant assumes that the co-pending application should have been U.S. Patent Application No. 09/616,731.

Applicant does not believe that a terminal disclaimer is necessary for the present application, but in the interest of expediency, a terminal disclaimer over U.S. Patent No. 6,908,770 and U.S. Patent Application 09/616,731 has been submitted.

C. The Claims Are Not Anticipated by Alberte Pursuant To 35 U.S.C. § 102(e)

The Examiner rejected claims 309, 311, 313-315, 317-321, 323, 325, 329, 330, 333, 335, and 337-339 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,692,696 to

Alberte et al. (hereinafter "Alberte"). Applicant respectfully disagrees that the claims are unpatentable over Alberte.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed.Cir. 1986); *In re Donahue*, 766 F.2d 531, 226 U.S.P.Q. 619, 621 (Fed.Cir. 1985).

The Office Action stated:

> Alberte discloses a system comprising a body, a light source disposed within the body (#36), a cartridge (#28), wherein the cartridge is removable and positionable within the body (Column 21, lines 50-62), wherein the cartridge comprises a body (#30) and a sensor array (#12, FIG. 7) wherein the array comprises a supporting member and at least one cavity within the supporting member (stage #32), particles positioned in the cavity (e.g. binding agent, cells or GPCR). (Office Action, page 3)

Amended claim 309 includes a combination of features including, but not limited to, the features of "a particle, wherein the particle is positioned in the cavity, and wherein the particle comprises a receptor coupled to a polymeric bead." Applicant's Specification states:

> The particles may include a receptor molecule coupled to a polymeric bead. The receptors, in some embodiments, are chosen for interacting with analytes. This interaction may take the form of a binding/association of the receptors with the analytes. (Applicant's Specification, page 8, lines 17-20); and
>
> The receptor molecules may be naturally occurring or synthetic receptors formed by rational design or combinatorial methods. Some examples of natural receptors include, but are not limited to, DNA, RNA, proteins, enzymes, oligopeptides, antigens, and antibodies. Either natural or synthetic receptors may be chosen for their ability to bind to the analyte molecules in a specific manner. In one embodiment, a naturally occurring or synthetic receptor is bound to a polymeric bead in order to create the particle. The particle, in some embodiments, is capable of both binding the analyte(s) of interest and creating a detectable signal. (Applicant's Specification, page 9, lines 14-22).

Alberte does not appear to teach particles that comprise a receptor coupled to a polymeric bead. Alberte appears to teach GPCRs on a cell surface.

Alberte states:

> A "G-Protein Coupled Receptor" (GPCR) is defined to be any cell surface transmembrane protein that when activated by the binding of a chemical ligand or specific substance, in turn activates a heterimeric guanine nucleotide-binding protein...In living cells, GPCRs are localized within cell membranes and operate to communicate chemical signals...from the extracellular environment to the inside of the cell. (Alberte, column 12, line 60 - column 13, line 1); and
>
> A GPCR is considered to be useful in those aspects of the present invention which employ cell-based sensors. In particular, the cells are transformed and heterologously express a GPCR that is coupled to an endogenous calcium channel. The term "heterologous expression" means transcription and translation of nucleotide sequences which are not native to the cell but which have been incorporated into the cell's chromosomal or extra-chromosomal expression system genetic engineering techniques known in the art. (Alberte, column 13, lines 41-49).

Additionally, Alberte appears to teach that the cells may be attached to a support. With respect to the support, Alberte states:

In a preferred embodiment, the cells 14 may be retained in a cartridge 28 by means of a binding agent 16 that is biologically compatible with the cells and provides nutrition for the cells. A preferred class of binding agents is hydrogels.
(Alberte, col. 22, l. 37-40)

Hydrogels provide a support for the attachment and growth (i.e. immobilization) of the cells. Formulated with nutritional media, hydrogels provide nutrition to cells as the hydrogel absorbs 30-90% by weight of biological fluids such as nutritional media. For example, yeast cells immobilized are in a hydrogel as a monolayer of cells to optimize cell exposure to the vapor containing the ligand of interest and optimizes detection of fluorescence changes by the monitoring means when the GPCR embedded in the host cells of the monolayer detect the ligand of interest.
(Alberte, col. 22, l. 56-65)

Alberte appears to teach attaching cells to a hydrogel support. Applicant submits that the hydrogel support described by Alberte does not appear to be a "polymeric bead". As such, Applicant submits that Alberte does not appear to teach or suggest using receptors coupled to polymeric beads. Applicant respectfully requests removal of the rejections to claim 309 and the claims dependent thereon.

The Office Action included a rejection of claim 311 in view of Alberte. Claim 311 includes the feature of "a sample input port, wherein the sample input is positioned on the body, and wherein the sample input port is coupled to the sensor array such that samples introduced into the input port are transferred to the sensor array" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 311 in combination with the features of claim 309.

The Office Action included a rejection of claim 313 in view of Alberte. Claim 313 includes the feature of "a sample input port and a filter, wherein the sample input is positioned on the body, and wherein the sample input port is coupled to the sensor array such that samples introduced into the input port are transferred to the sensor array, and wherein the filter is coupled to the sample input port" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 313 in combination with the features of claim 309.

The Office Action included a rejection of claim 314 in view of Alberte. Claim 314 includes the feature of "a fluid cartridge coupled to the body and the sensor array" in combination with the features of claim 309. Applicant's Specification states:

> In one embodiment, all of the necessary fluids required for the chemical/biochemical analyses are contained within the portable sensor array system. The fluids may be stored in one or more cartridges 1050. The cartridges 1050 may be removable from the portable sensor array system. Thus, when a cartridge 1050 is emptied of fluid, the cartridge may be replaced by a new cartridge or removed and refilled with fluid. The cartridges 1050 may also be removed and replaced with cartridges filled with different fluids when the sensor array cartridge is changed. Thus, the fluids may be customized for the specific tests being run. Fluid cartridges may be removable or may be formed as an integral part of the reader. (Applicant's Specification, page 170, lines 5-12).

Alberte states "[e]xposing means 22 typically include a flow chamber in which the cartridge 28 is mounted for intaking a vapor stream or a liquid stream containing a candidate substance." (Alberte, column 22, line 66 - column 23, line 1). Alberte appears to teach a flow

chamber that intakes vapor or liquid streams. Alberte does not appear to teach or suggest a fluid cartridge. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 314 in combination with the features of claim 309.

The Office Action included a rejection of claim 315 in view of Alberte. Claim 315 includes the feature of "an electronic controller disposed in the body and coupled to the sensor array, the light source, and the detector; wherein the electronic controller is configured to control the operation of the sensor array system" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 315 in combination with the features of claim 309.

The Office Action included a rejection of claim 317 in view of Alberte. Claim 317 includes the feature of "a data transfer system" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 317 in combination with the features of claim 309.

The Office Action included a rejection of claim 318 in view of Alberte. Claim 318 includes the feature of "wherein the detector comprises a monochrome detector" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 318 in combination with the features of claim 309.

The Office Action included a rejection of claim 319 in view of Alberte. Claim 319 includes the feature of "wherein the detector comprises a color detector" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 319 in combination with the features of claim 309.

The Office Action included a rejection of claim 320 in view of Alberte. Claim 320 includes the feature of "wherein the light source comprises at least one light-emitting diode" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 320 in combination with the features of claim 309.

The Office Action included a rejection of claim 321 in view of Alberte. Claim 321 includes the feature of "wherein the light source comprises a light emitting diode" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 321 in combination with the features of claim 309.

The Office Action included a rejection of claim 323 in view of Alberte. Claim 323 includes the feature of "a fluid delivery system coupled to the supporting member" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 323 in combination with the features of claim 309.

The Office Action included a rejection of claim 329 in view of Alberte. Claim 329 includes the feature of "wherein the particle further comprises a first indicator and a second indicator, wherein the first and second indicators are configured to be coupled to a receptor, wherein the interaction of the receptor with the analyte causes the first and second indicators to interact such that the signal is produced" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 329 in combination with the features of claim 309.

The Office Action included a rejection of claim 330 in view of Alberte. Claim 330 includes the feature of "wherein the particles further comprises an indicator, wherein the indicator is associated with a receptor such that in the presence of the analyte the indicator is displaced from the receptor to produce the signal" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 330 in combination with the features of claim 309.

The Office Action included a rejection of claim 333 in view of Alberte. Claim 333 includes the feature of "wherein the supporting member further comprises a barrier layer positioned over the cavity, wherein the barrier layer is configured to inhibit dislodgment of the particle during use" in combination with the features of claim 309. Applicant respectfully

submits that the cited art does not teach or suggest the features in claim 333 in combination with the features of claim 309.

The Office Action included a rejection of claim 335 in view of Alberte. Claim 335 includes the feature of "wherein the supporting member further comprises a barrier layer positioned over the cavity, wherein the barrier layer is configured to inhibit dislodgment of the particle during use" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 335 in combination with the features of claim 309.

The Office Action included a rejection of claim 337 in view of Alberte. Claim 337 includes the feature of "wherein the cavity is configured such that the fluid entering the cavity passes through the cavity during use" in combination with the features of claim 309. Alberte appears to teach fluid (arrows in FIGS.) flowing over the cartridge body (30) during use. (FIGS. 1-3). Alberte does not appear to teach or suggest a cavity configured such that fluid entering the cavity passes through the cavity during use. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 337 in combination with the features of claim 309.

The Office Action included a rejection of claim 338 in view of Alberte. Claim 338 includes the feature of "a pump coupled to the supporting member, wherein the pump is configured to direct the fluid towards the cavity" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 338 in combination with the features of claim 309.

The Office Action included a rejection of claim 339 in view of Alberte. Claim 339 includes the feature of "wherein a channel is formed in the supporting member, wherein the channel couples a pump to the cavity such that the fluid flows through the channel to the cavity during use" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 339 in combination with the features of claim 309.

D. The Claims Are Not Obvious Over Alberte In View Of Stabile Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claims 324, 326-328, 331, 332, 334, 336, and 340 under 35 U.S.C. § 103(a) as being obvious over Alberte in view of U.S. Patent No. 5,872,623 to Stabile et al. (hereinafter "Stabile"). Applicant respectfully disagrees that the claims are unpatentable over Alberte in view of Stabile.

A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993); *see also In re Kotzab*, 217 F.3d 1365, 1371(Fed. Cir. 2000); MPEP 2143.01.

The Office Action states:

> Alberte discloses a system comprising a body, a light source disposed within the body (#36), a cartridge (#28), wherein the cartridge is removable and positionable within the body (Column 21, lines 50-62), wherein the cartridge comprises a body (#30) and a sensor array (#12, Fig. 7) wherein the array comprises a supporting member and at least one cavity within the supporting member (stage #32), a particles positioned in the cavity...Alberte does not teach the detector comprises a charge-coupled device; a plurality of particles in a plurality of cavities, wherein the particles ranges from about 0.05 microns to about 500 microns wherein the volume of the particle changes when contacted; wherein the supporting member comprises silicon; a transparent barrier over the cavity to provide a channel; or a dry film photoresist...However these elements were well known in the art and routinely practiced as taught by Stabile who teach a similar device comprising a substrate having cavities with particles therein. (Office Action, page 6-7).

Applicant submits that Alberte and Stabile do not teach similar devices and there is no motivation to combine the references. Alberte appears to teach GPCRs on a cell surface.

(Alberte, column 12, line 60 - column 13, line 1). Alberte also appears to teach immobilizing a cell in a hydrogel. (Alberte, column 18, lines 23-25; column 22, lines 18-23, 37-40) Alberte does not appear to teach particles or a particle positioned in a cavity. Alberte also teaches "multiple sensing elements in multiple demountable cartridges that include GPCRs which are preferentially responsive to the specific substance." (Alberte, column 27, lines 46-48).

Stabile states:

> The reaction cells or detection sites are preferably found on a planar substrate 105 that is separable from the portion of the liquid distribution system containing reservoirs and pumps. The separable planar substrate 105 docks with the liquid distribution system, typically with a gasket material (that has openings at appropriate locations) interposed between the two, so that the cells are aligned underneath the appropriate outlet for delivering liquid from the liquid distribution system. (Stabile column 14, lines 1-9)

Stabile appears to teach a substrate that is removable from a liquid distribution system. Stabile does not appear to teach or suggest a body including a light source and detector and a sensor array within a cartridge that is removable from the body. Applicant submits that there is no motivation to combine the demountable cartridges that include cells immobilized in hydrogel of Alberte with the system of Stabile.

In addition, Applicant submits that the references do not appear to teach all the features of the claims. Claims 324, 326-328, 331, 332, 334, 336, and 340 depend on claim 309 which includes a combination of features including, but not limited to, the features of "a particle, wherein the particle is positioned in the cavity, and wherein the particle comprises a receptor coupled to a polymeric bead."

For at least the reasons previously mentioned Alberte does not appear to teach or suggest all the features of the claims. Stabile states "detection site volume and depth are selected to help accommodate the insertion of beads on which synthetic or other chemistries are conducted." (Stabile, column 13, line 41-43). Stabile does not appear to teach or suggest particles comprising a receptor coupled to a polymeric bead. Applicant submits the cited art does not teach or suggest

at least the quoted features of the claim. Applicant respectfully requests removal of the rejection to claim 309 and the claims dependent thereon.

The Office Action included a rejection of claim 324 in view of Alberte and Stabile. Claim 324 includes the feature of "wherein the detector comprises a charge-coupled device" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 324 in combination with the features of claim 309.

The Office Action included a rejection of claim 326 in view of Alberte and Stabile. Claim 326 includes the feature of "wherein the system comprises a plurality of particles positioned within a plurality of cavities, and wherein the system is configured to substantially simultaneously detect a plurality of analytes in the fluid" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 326 in combination with the features of claim 309.

The Office Action included a rejection of claim 327 in view of Alberte and Stabile. Claim 327 includes the feature of "wherein the particle ranges from about 0.05 micron to about 500 microns" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 327 in combination with the features of claim 309.

The Office Action included a rejection of claim 328 in view of Alberte and Stabile. Claim 328 includes the feature of "wherein a volume of the particle changes when contacted with the fluid" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 328 in combination with the features of claim 309.

The Office Action included a rejection of claim 331 in view of Alberte and Stabile. Claim 331 includes the feature of "wherein the supporting member comprises silicon" in

combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 331 in combination with the features of claim 309.

The Office Action included a rejection of claim 332 in view of Alberte and Stabile. Claim 332 includes the feature of "wherein the supporting member further comprises channels in the supporting member, wherein the channels are configured to allow the fluid to flow through the channels into and away from the cavity" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 332 in combination with the features of claim 309.

The Office Action included a rejection of claim 334 in view of Alberte and Stabile. Claim 334 includes the feature of "wherein the supporting member further comprises a barrier layer positioned over the cavity, wherein the barrier layer is configured to inhibit dislodgment of the particle during use, and wherein the barrier layer comprises a substantially transparent cover plate positioned over the cavity, and wherein the barrier layer is positioned such that a channel is formed between an upper surface of the supporting member and the barrier layer, and wherein the fluid passes through the channel during use" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 334 in combination with the features of claim 309.

The Office Action included a rejection of claim 336 in view of Alberte and Stabile. Claim 336 includes the feature of "wherein the supporting member comprises a dry film photoresist material" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 336 in combination with the features of claim 309.

The Office Action included a rejection of claim 340 in view of Alberte and Stabile. Claim 340 includes the feature of "a vacuum apparatus coupled to the sensor array, wherein the vacuum apparatus is configured to pull the fluid through the cavity during use" in combination

with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 340 in combination with the features of claim 309.

E. The Claims Are Not Obvious Over Alberte In View Of Wilding Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claim 312 under 35 U.S.C. § 103(a) as being obvious over Alberte in view of U.S. Patent No. 5,587,128 to Wilding et al. (hereinafter "Wilding"). Applicant respectfully disagrees that the claims are unpatentable over Alberte in view of Wilding.

The Office Action included a rejection of claim 312 in view of Alberte and Wilding. Claim 312 includes the feature of "further comprising a sample input port, wherein the sample input is positioned on the body, and wherein the sample input port is coupled to the sensor array such that samples introduced into the input port are transferred to the sensor array, and wherein the sample input port is configured to receive a syringe" in combination with the features of claim 309. Applicant respectfully submits that the cited art does not teach or suggest the features in claim 312 in combination with the features of claim 309.

F. Summary

Applicant submits that all claims are in condition for allowance. Favorable reconsideration is respectfully requested.

A Fee Authorization is enclosed for the terminal disclaimer fee. If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any fees have been omitted or if any additional fees are required, please charge those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5936-00529/EBM.

Respectfully submitted,

Mark R. DeLuca
Reg. No. 44,649

Patent Agent for Applicants

MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.
P.O. BOX 398
AUSTIN, TX 78767-0398
(512) 853-8800 (voice)
(512) 853-8801 (facsimile)

Date: 9/6/05